Statement of Purposes

1. Purpose of Collection

The personal data that are provided by you in connection with this Report Form or when you are in contact with the Department of Health (DH) in connection with in this Report Form will be used by the DH for medical device adverse event investigation and management.

The provision of personal data is voluntary. If you do not provide sufficient information in the Report Form as specified, we may not be able to provide assistance to you.

2. Classes of Transferees

The personal data you provided are mainly for use within the DH but they may also be disclosed to other Government bureaux / departments, or relevant parties for the purpose mentioned in paragraph 1 above, if required. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.

3. Access to Personal Data

You have a right to request access to and correction of your personal data as provided in accordance with the Personal Data (Privacy) Ordinance (Cap. 486).
Your right of access includes the right to obtain a copy of your personal data provided during the occasion as mentioned in paragraph 1 above. A fee may be imposed for complying with a data access request.

4. Enquiries

Enquiries in relation to the personal data, including requests for making access or corrections to the data, should be addressed to:

Executive Officer
Medical Device Division, Department of Health
Room 604, 6/F, 14 Taikoo Wan Road,
Taikoo Shing, Hong Kong
Telephone number: 3107 8453
E-mail address: mdd@dh.gov.hk.

Please quote our file reference number when submitting the request.

MEDICAL DEVICE DIVISION
Medical Device Adverse Event Report Form – for Medical Device Users

This is a voluntary report form for reporting suspected problem with a medical device that may present a hazard. Submission of this report does not constitute an admission by the reporter of liability for the event and its consequences. It is also not a conclusion that the device caused or contributed to the adverse event. For enquiries, please contact the MDD at telephone no. 3107 8484.

MDD Report No.

(Official Use Only)

I. DEVICE INFORMATION

1.	Device Description			
2.	Brand Name and Model			
3.	Serial No., Batch No., or Lot No.		4. MDD Listing No. (if known)	

5. Is the device or its packaging available for inspection? ☐ Yes ☐ No

II. SUPPLIER INFORMATION

1.	Company Name			
2.	Name of Contact Person		3. Telephone No.	

4. Have you reported this problem to other parties?

☐ No ☐ Yes, please provide the name of the company, the name of the contact person, the telephone no. and the report date:

Name of Company: _____ Name of Contact Person: _____

Telephone No.: _____ Date of Report: _____

III. PROBLEM DESCRIPTION

1. Please give a brief description of the problem:

2. Consequence of the problem: ☐ Death ☐ Serious Injury ☐ Might lead to death or serious injury if recurs ☐ Nil

Please elaborate:

IV. REPORTER INFORMATION

1.	Name of the Organization			
2.	Name of the reporter		3. Position	
4.	Contact Telephone No.		5. Contact Fax. No.	
6.	E-mail Address		7. Date of Report	

V. SUBMISSION OF REPORT

1.	By Mail:	Medical Device Division Department of Health Room 604, 6/F, 14 Taikoo Wan Road, Taikoo Shing, Hong Kong	2. By Fax.: (852) 3157 1286 3. By E-mail: mdd_air@dh.gov.hk